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Food Safety Toolkit Introduction and Quick Start Guide

Investment Climate | World Bank Group



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About the Investment Climate Department of the World Bank Group

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Table of Contents

Foreword	5
Acknowledgements	9
Acronyms	11
Quick start guide	13
Importance of food safety regulation to private business development	21
Internal market development and growth	23
Purpose of the Toolkit	25

Foreword

Demand for food safety regulatory reform can come from many quarters: domestic businesses, exporters, traders, retailers, foreign investors, and most importantly, consumers. Well-crafted regulations can guide and assist domestic farmers and firms to effectively compete with imports or allow them to access new export markets. As the agricultural sector in a developing country evolves and the quality and breadth of food processing increases, establishing a viable food safety system is a key element of success.

This Toolkit aims to empower reformers with a suite of tools to assess market potential, build capacity, and assist in mitigating barriers to development in the area of food safety. The Toolkit tackles each step in the reform process. It examines the related system development in a strategic way supported by best practice examples and sound principles of institutional structure and legislative reform. Risk-based approaches to regulation and regulatory delivery are considered alongside the need for flexible and proportionate responses to both.

continued on next page



Foreword

Design of the Investment Climate Food Safety Toolkit builds on the IFC's Sustainable Business Advisory Food Safety Toolkit which sets out practical tools and techniques for verification of effective food safety systems at the firm level. These two complementary tools, addressing both public and private sector dimensions to the development and implementation of effective food safety systems, can form the basis of a public private partnership that fosters reform and growth. Products, sectors and entry points may vary but the need for confidence in the safety and quality of the products produced for the benefit of both markets and citizens remains constant.



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Acronyms

APLAC	Asia Pacific Accreditation cooperation	SPS	Sanitary and Phytosanitary
BAP	Best Aquaculture Practice	SQF	Safe Quality Food
BRC	British Retail Consortium	USAID	U.S. Agency for International Development
CAC	Codex Alimentarius Commission	USDA	U.S. Department of Agriculture
CAS	Country Assistance Strategy	WHO	World Health Organization
CFIA	Canadian Food Inspection Agency	WTO	World Trade Organization
CPS	Country Partnership Strategy		
EAL	European Cooperation for Accreditation of Laboratories		
EC	European Commission		
EAC	East African Community		
EFSA	European Food Safety Authority		
EU	European Union		
FAO	Food and Agricultural Organization		
FBO	Food business operators		
GDP	Gross Domestic Product		
GAP	Good agricultural practices		
GFSI	Global Food Safety Initiative		
GHP	Good hygiene practices		
GMO	Genetically modified organisms		
GMP	Good management practices		
GRMS	Global Red Meat Standard		
HACCP	Hazard Analysis Critical Control Point System		
ILAC	International Laboratory Accreditation Cooperation		
KDB	Kenya Dairy Board		
KEBS	Kenya Bureau of Standards		
LIMS	Laboratory Integrated Management System		
NGOs	Nongovernmental organizations		
ILAC	International Laboratory Accreditation Cooperation		
IPPC	International Plant Protection Convention		
OECD	Organisation for Economic Co-operation and Development		
OIE	World Organization for Animal Health		
PCB	Pest Control Products Board		
PRPs	Prerequisite Programs		
RFID	Radio frequency identifier		
SBA	Sustainable Business Advisory		

Introduction and Quick Start Guide

MODULE 1

Introduction and Quick Start Guide

MODULE 2

Guiding principles of food safety reform

For all projects related to food safety reform, the following guiding principles should be kept in mind:

- Regulation and official controls by themselves cannot ensure food safety.
- Primary responsibility (and liability) for the safety of food rests on food business operators.
- Food safety should be secured across the entire food chain.
- A preventative and risk-based approach should be the basis for regulatory reform, decision making, and control and self-control of food safety.
- International standards and scientific justification should form the basis of all regulatory measures.
- The impact of food safety reform on trade, consumer prices, economic output, and jobs should be carefully considered – costs and negative impacts can be significant from an economic perspective.
- The food safety system will always involve multiple players; coordination and collaboration are vital.

NOTE: NOT ALL PROJECTS WILL GO THROUGH ALL THE FOLLOWING STEPS – SELECTING WHAT WILL BE COVERED WILL BE BASED ON THE PROJECT SCOPE AND DESIGN AS DEFINED ABOVE, DEPENDING ON COUNTRY NEEDS, CAPACITY, RESOURCES, AND THE SPECIFIC ROLE OF THE INVESTMENT CLIMATE DEPARTMENT OF THE WORLD BANK GROUP.

MODULE 3

Legislative reform

For a food safety reform project to be successful, it is not enough to alter only texts in legislation, or structures in the government or processes in inspectorates. It involves a different way of thinking by many people and a change in attitudes and behaviors. This can be the most difficult part of the project and easily underestimated or even overlooked. Applying food safety reform can in many countries be an extremely radical change in fundamental assumptions about safety and about the role of the state.

It is important to be clear about the starting point and destination. For countries that are realistic candidates for European Union accession, the destination is a pre-existing package of legislation within the EU system and this path has been followed by a number of other accession countries previously. For countries not in line for EU accession the destination may be joining other trade agreements and there may be in some cases similarly clear packages of food safety regulations to adopt. For other countries, getting a clear vision of the destination can be difficult and the timescale for that journey can be challenging and often insufficiently thought through. The World Trade Organization Sanitary and Phytosanitary (WTO SPS) agreement provides a general framework, but many details have to be fleshed out in each specific case.

Introduction and Quick Start Guide

To assess the starting point for any legislative reforms, you have to have a good grasp of how the current system operates and how embedded it is in institutions, practices, and the culture of practitioners as well as of businesses and consumers. It is also essential to think about capacity of economic operators and regulators and about consumer incomes and education. It is not simply a matter of aligning legislative texts or of aligning systems and thinking. Depending on the conditions and objectives, the legislation may be:

- close to EU legislation;
- similar to international best practices; or
- not closely based on a foreign model.

These are some key questions to ask:

- Is the pre-existing system based on standards, on testing, and on blanket inspections (trying to inspect each and every business, process and product)?
- Have any of the norms and standards been aligned with international standards?
- Can the legislation be identified clearly as being about food safety or is it mixed with issues of food supply and food quality?
- What is the implementation capacity, existing problems in enforcing applicable legislation, and what challenges are to be expected in bringing reformed legislation to life?

Introduction and Quick Start Guide

MODULE 4

Institutional structure

Start from a map of the current distribution of responsibilities and roles, which are likely to be spread across a range of ministries, agencies, and inspectorates. The field of food safety impinges on many other policy areas, and the particular distribution of roles in a country is likely to be unique in its detail but common in its complexity. Many agencies are typically in charge of various aspects of the food safety issue – from animal breeding through plant protection chemicals, processing, transport, catering, up to human health at the end of the chain.

It is generally easier to try to unify the implementation part of the food safety system (control, inspections, supervision, testing, enforcement) than the policy inputs (that is, setting rules and requirements on all aspects (production, animal health, chemicals, water, residue levels in food). Therefore, much can be done with a single inspectorate, even if regulations are issued by more than one ministry or agency.

There may be a strong desire to try and set up a single food safety agency that covers policy and implementation, but such institutions are quite rare. It may not be appropriate or feasible for a particular country, or the political opposition may be too great.

Although there is probably a preference internationally for a single agency, at least in terms of inspections, it does not have the status of international best practice, precisely because of the complexity and peculiarities of other government structures. It is very rare in practice to have an agency that covers the entire food chain from primary production (veterinary, phytosanitary) to retail and catering. Most “single” agencies cover only a part of the chain (even though a major one).

It is essential to aim at consolidation as much and as effectively as possible in the context, and in the perspective of what the Food and Agricultural Organization (FAO) defines as the “integrated model.” Under such a model, all institutions involved in food safety regulation have clearly defined and articulated roles, and are fully interconnected so that regulation and supervision are not overlapping or duplicated, and are coherent and consistent throughout the food chain. Ensuring that there is no duplication or overlap in control and supervision should be a priority – and, where possible, consolidation of as many of the control and supervision functions in a single food safety inspectorate as well. If further consolidation can be achieved, it will be a positive step. But if consolidation is politically difficult or impossible, many other aspects are important and the reform team should not expend all energies on this goal to the detriment of others.

Introduction and Quick Start Guide

MODULE 5

Risk assessment, enforcement, and inspections

Institutional change alone will not bring success without also reforming the approach taken to inspections, both by the inspectorate in terms of process and the inspector in terms of attitude. Institutional change may help in tackling these other issues, but it should not be expected to transform them by itself. In fact, excessive attention given only to the institutional framework can distract from looking at real inspection practices, which is a real risk for project success.

The person who is asked to change the most is the inspector. Again, it can be presented as leading to greater job satisfaction and increased respect and status but that may seem unrealistic to them, whereas the likelihood of losing the opportunity to supplement an often extremely low salary is a much more immediate and real prospect. Additional difficulty comes from the fact that achieving broader reforms that would improve the status and compensation package of inspectors is often very difficult for political, financial, and other reasons. It is important that the project provides good quality training to equip inspectors for a more challenging role and, ideally, entitle him to an increased salary, if the context allows. Developing the competence of individual inspectors can be one of the fundamental aims of the project. In many countries, the inspection system is geared more towards opportunities for rent-seeking than a serious attempt to tackle the risks arising from unsafe food. The more often an inspector has some justification to go into a business, the greater the opportunity for collecting rents.

In most unreformed systems, it is assumed that blanket inspection is the best way of providing protection but modern thinking and experience has invalidated that model. Comprehensive inspection of each and every product and establishment is impossible in practice because it requires resources to be spread too thinly. Trying to control all products and premises through inspection will usually mean that the highest risk areas are not being tackled, can lead to badly implemented checks (including rent-seeking behaviour of inspectors) and also leads to unnecessary administrative burdens.

Targeting inspection resources on the highest risks where they are likely to have the greatest effect is a major change that will often be difficult to achieve. The basis for food safety reform of inspections is the application of risk in identifying which establishments and products are most likely to present the greatest danger. Applying this approach requires designing risk criteria suited to the dangers being tackled; information about the compliance record of businesses; and the likelihood of their continuing compliance. This practice will lead to a risk matrix and data that will allow establishments to be categorized as high, medium, or low risk. The categorization then allows for a plan of inspections that starts to make the process more transparent and targeted.

Introduction and Quick Start Guide

MODULE 6

Principles of food safety management

A food safety system is based on the concept of the “food chain,” from start to finish, from the plant or livestock to the meal on the family table. That can involve the grower / farmer, the slaughterhouse, the transporter, the food production factory, again the transporter, the warehouse, the retailer, and then the customer.

In most countries, there is a scientific infrastructure already in place to some extent but its role and function may be radically different to what is needed in a modern approach (and in some countries it may be entirely or mostly missing). In most unreformed systems, science is used after the event, testing the end product but doing little to increase the chances that such a product will in fact be safe.

Production of food is not as uniform as production of goods, and scientific testing needs to be of the whole process, not just a few final products. The scientific basis of the reformed systems of food safety relies on gathering good evidence (on the whole food chain) and building on that through a process of risk analysis to devise the optimum system. The emphasis is on better systems leading to safer products, and this is enshrined in the Hazard Analysis Critical Control Point System (HACCP), which checks where the likely dangers will be in the process and takes steps to manage the risks at these points in a highly disciplined and regular system.

The HACCP system relies on the existence and implementation of functional “prerequisite programs” in place securing a basic level of hygiene and safety. HACCP is a relatively recent introduction in most countries where it is in force, and what are now referred to as “prerequisite programs,” fundamental hygiene and safety requirements have long been enough to ensure an adequate level of food safety in most contexts. For many small businesses, applying these is enough to secure safety of products since their operations are simple and number of inputs limited.

Laboratories are an opportunity and a challenge to the project because they are both important and expensive. It is impractical to use them for blanket testing of products and, again, scarce resources need to be targeted where they will be most effective. Depending on distances to be covered, it is preferable to have a network of laboratories where some will specialize in particular tests or products (“reference laboratories”). This is a more effective way of organising scientific infrastructure but does not work if it takes three days for the sample to reach it.

Laboratories carry out testing to:

- confirm whether a suspected product is in fact dangerous; and
- provide certification of food in a way that will ease external trade and avoid further re-certification procedures in the importing country

Unfortunately, the latter is possible only if the domestic laboratory has international accreditation and this is usually beyond the resources of developing countries.

Introduction and Quick Start Guide

The question of scientific underpinning and infrastructure is difficult because it relates so strongly to the country's capacity at the government and business levels, and also because it may involve very significant involvements. For that reason, reform efforts need to have a clear view of the issues and needs, but be realistic about what can be tackled. In this situation, co-ordination with other donors is essential.

The cornerstone in making the food chain work is that of "producer responsibility." Individuals at each stage of the chain are responsible for the safety of the food under their control. Each person is accountable to the next party in the chain, who in turn is responsible to the next. If there is choice, there is competition to both buy the best and sell the best and, in this way, the chain reinforces safety. If there is no choice or if there is a very short supply chain, the system is less effective, although the principles still apply.

"Producer responsibility" is a major change for many countries, where the existing model is the outdated "regulator responsibility" model where safety is expected to result from a high level of state controls by regulators. This shift toward producer responsibility is both essential and very difficult to achieve.

The businesses themselves also need to understand their new responsibilities and the new dynamics in the market. It is fortunate that these reforms are generally in the commercial interests of business development, at least in the long run. But in the short term, or for many existing businesses, the costs may outweigh the benefits, if things are not properly designed and planned. The businesses also need to understand their new responsibilities and the new dynamics in the market and that at the end of the day, businesses that implemented food safety principles will be better able to compete in the market race. Applying internal control systems may seem to be an unwelcome overhead but they tend to be excellent business investments. There is a selling job to do with businesses but the emphasis is strong on evidence. It is in your interest when managing an project, to encourage more businesses to enter the market as food business operators (FBOs). One of the first reforms is to reduce the common barriers to entry that new businesses usually face, in terms of approvals (such as permits and licenses) and examinations before starting up. Experience and research have shown that, in most cases, such entry barriers bear high economic costs in terms of reducing competition and growth, while delivering only limited benefits in terms of safety. Indeed, checking before start of operation is highly deterrent and costly – but says little about how operations will really run.

Some FBOs dealing with particularly high risk processes or products do still require approval to enter the market (for example, slaughterhouses, meat and dairy processing factories) but, for non high risk FBOs, registration should simply be a matter of informing the authorities that it is about to start a business of a particular kind. That brings the FBO within the system. Checks on its suitability and compliance can be performed later, rather than before business startup, which poses a barrier to entry.

The principle of traceability is also needed to make a food chain work. At each link in the chain, the FBO needs to know who supplied specific products and needs to record the next recipient of these products. This "one step down – one step up" approach should not be a particularly burdensome overhead in a well-run business (although it can start to become complicated in

Introduction and Quick Start Guide

a factory where raw materials are transformed into new products) – but it will be difficult to bring about in least developed markets with low-capacity operators.

In most developing countries where food safety reform is a relatively new or large undertaking, traceability requirements should be phased in – focusing first on some priority sectors and commodities, in particular those destined for export. This means that operators' and regulators' capacity can be gradually built, needed investments done, and success in these "flagship" sectors can later be replicated for other productions.

Following the principle of traceability is the ability to recall products when a problem is found. This may be a voluntary withdrawal or recall by the producer or it may be mandated by the control body. Effective traceability records allow the possibility of quickly tracking back from an unsafe product to its source and then tracking forward to see where else that product has been distributed and may pose a danger. Because problems are bound to happen, however robust the rest of the food safety system, the ability to identify the source of outbreaks (traceability) and react effectively to them (withdrawals and recalls) is vital.

MODULE 7

Implementation, monitoring and evaluation

Although the reformed system is actually putting in place a far stricter and far greater number of tests because it works through the internal systems of the producer, what may be visible to the public is an apparent reduction in official testing and inspections. Given that the previous system was based fundamentally on extensive testing and inspection, this may understandably give the impression that the state is abdicating responsibility and that it is a free-for-all for unscrupulous businesses. It is therefore very important for the project to support public discussion and communication prior to reform to demonstrate the ways in which the "pre-reform" system is not really effective in securing consumer safety (even though data may be sometimes difficult to find come by, this is usually possible).

Practitioners also need to build in the capacity for monitoring and evaluation (M&E) as they design and develop the project, rather than M&E being an add-on. Module 7 makes the vital distinction between outputs and outcomes and suggests various outcome measures.

MODULE 8

Case studies

Module 8 has various case studies to inspire and guide. They were selected to reflect experiences in various regions and give examples of different approaches, models, issues, and challenges covered in this toolkit.

Importance of food safety regulation to private business development

Food safety is primarily, by its nature, a public health issue, which means that the involvement of the Investment Climate Department of the World Bank Group in this sphere may seem far from obvious. To most, food safety does not readily appear to be a private sector development or an investment climate issue. In fact, the ability to produce safe food and to be trusted by potential customers is crucial to integration in international trade for food producers – meaning that food safety systems are a key issue for the private sector. At the same time, food safety regulations can also impose a heavy administrative burden on businesses. There are thus several perspectives from which food safety is a highly relevant issue to the Investment Climate Department of the World Bank Group.

Ensuring that the food safety regulatory system works effectively, efficiently, and with the least possible burden is in fact key to private sector development in more ways than one. First, an effective food safety system is key for access to external markets. Second, a robust and trusted food safety system is key to growing the country's own internal market, and the ability of local firms to position themselves on higher value-added market segments. Even though there are other important aspects in which food safety impacts private sector growth, these are the most essential in terms of involvement by the Investment Climate Department of the World Bank Group.

Access to international markets and competitiveness

The existence in a given country of a robust, reliable and effective food safety system, and one that is (a key point) recognized as such by foreign countries, is crucial to the realization of this country's export potential. For certain types of food products, having such a system is a requirement for access to certain markets (for example, the EU). In all cases, whichever the product, not having such a system means a serious competitive disadvantage for a country's producers, who will gener-



ally be confined to the lowest-profit markets, lowest-margin types of products, and mostly excluded from international supply chains.

This is an essential development issue because many developing countries and emerging markets have considerable, but incompletely realized, potential for agricultural or animal production and transformation thereof into processed food products. In many of these countries, however, the food safety system suffers from one or several weaknesses:

- Requirements and norms are not in line with internationally accepted practices.
- Laboratory testing and monitoring of animals and foodstuffs is unreliable.
- Inspections and controls are poorly planned, implemented, and coordinated.

As a result, these countries' food safety regulatory systems are seen by potential customers as not offering acceptable guarantees. For more hazardous types of goods (for example, foods of animal origin) and the most demanding markets (for example, the EU) it means exporters from these countries may be entirely barred from access, or be allowed access to a narrow range of goods.

For less hazardous goods such as rice, weak food safety systems may not mean access to the richest markets is entirely impossible, but it is made more difficult, and with a worsened competitive position. Producers from these "low food safety" countries will usually only be able to sell their products through middlemen that blend them with other products (and do so in establishments located in more reliable countries in terms of food safety), or as lowest grade, lowest price goods. In fisheries, the lack of a reliable food safety system often means that natural resources are harvested by others' fleets, with only minimal income left in the country, if any (for example, the current situation in Guinea).

Even major markets, to which exporters from "low food safety" countries have traditionally had access, such as the Russian Federation, are now gradually tightening their requirements. This means the position of exporters from countries in Central Asia, for example, becomes even more critically dependent on improvements in these countries' food safety systems.

The priority level of food safety regulation improvements for the private sector thus to some extent depend on the type of products to be exported (animal or plant) and the target markets. But increasingly, even for lower-risk products, not having appropriately trusted food safety systems in the country means that exporters are shut out of the main supply chains that lead to the major wholesalers and retailers, and confined to regional markets, with lower prices. Weak food safety systems also mean that processing of any kind will not take place in the country. Instead, only raw foodstuffs will be exported to be processed and conditioned elsewhere, thus taking a large portion of the potential value-added out of the country.



Internal market development and growth

An unreliable food safety system is not only harmful to a country's ability to access and compete on world markets, it can also seriously burden firms in country, and also harm the development of the internal market.

Ineffective food safety regulations can also prove to be burdensome to business. For example, in many countries there are frequent checks and inspections without relation to the risk level of the business operation and/or numerous permits and licensing requirements. Ineffective food safety regulations can often discourage the introduction of new products and technologies because of outdated and highly prescriptive requirements. All this means that, even without taking into account the impact on exports (or potential exports) these regulatory systems can create real barriers to growth.

In addition, ineffective food safety regulations can slow down or hamper the development of internal markets in ways that harm countries' long-term competitiveness. Indeed, if food safety regulation is not seen by domestic consumers as reliable, they will be reluctant to spend more for safer, higher value-added foods – and/or they will only be happy to spend more on imported foods or foreign brands, which they see as more reliable than local ones. Alternatively, consumers may have more trust in local producers because of "traditions." In all cases, this means there is no incentive for domestic producers to invest in improving the safety level of their foods, as they will neither gain market share nor be able to demand higher prices, given that consumers will not trust that such foods are indeed safer. As a result, domestic firms will be less likely to invest in food safety improvements, which will in turn make their international competitiveness worse in the long run.

Creating trust enables local growers, herders, processors, and distributors to reap the benefits of investments in safety and quality. In this way, they not only generate growth and create better jobs, but they also prepare themselves better to participate in international markets.

Well-designed food safety regulatory systems, if control and implementation are adapted to the development level and properly risk-based, can deliver improved safety and increased trust while generally decreasing administrative burden. In most cases, such systems can facilitate innovation and technology adoption in terms of products and processes. This is because effective systems rely only to a small extent on permits and licenses or mandatory certification, and because inspections and controls are made proportional to risk. Thus, improving food safety can also lead to an actual decrease in the overall regulatory burden for many businesses.

In addition to the main economic benefits provided by improved access to international markets, increased differentiation on the internal market and, in many cases, decreased administrative barriers to innovation and growth, improved food safety regulations can deliver some additional positive outcomes. For instance, even though the link is not always direct, improved food safety in a country can bring a positive contribution to the tourism industry by improving this country's image, and making it more attractive for "mainstream" and higher-income tourists. Also, improved food safety means a significant (and in some case major) reduction in foodborne diseases, reducing health costs, loss of lives, and disabilities. This takes away a major source of insecurity for the more vulnerable households and improves overall productivity. These health benefits are also a major contributor to economic growth.

Purpose of the Toolkit

The purpose of this Investment Climate Food Safety Toolkit is to provide reformers, project teams supporting reforms, and policymakers with an overview of the principles of food safety reform, the primary objectives, key instruments and critical success factors, as well as provide a number of specific examples and case studies. The Toolkit is aimed at supporting work on food safety and inspections reform to support development of the agribusiness sector.

This toolkit may also be used as a guidance document for external audiences, such as partners and stakeholders in reform programs, so that they can understand the scope of food safety reform, the importance of collaboration of public and private sectors, the value of education of all involved parties, the importance of transparency, and the strength of the market-driven approach.

This toolkit focuses on the overall architecture of food safety regulation and answers the following questions:

- What does it entail?
- What other components form the “food safety system” and are essential for it to work effectively?
- What are the key elements of best practice (and what elements are disputed)?
- What can interventions by the Investment Climate Department of the World Bank Group focus on (and achieve)?

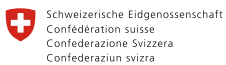
This toolkit emphasizes the roles of all players in the food chain, including food business operators and states providing the regulatory and control environment.

The Toolkit emphasizes solutions and approaches that are realistic, and conducive to private sector development and broad-based, inclusive growth. At the same time it warns against potential pitfalls, including the danger of “gold plating” and the introduction of regulatory requirements that are not commensurate to the level of development of the country or of its businesses.

Finally, it should be noted that the Toolkit does not attempt to provide full, in-depth prescriptions on all aspects of food safety regulations, as this would both make the Toolkit unwieldy and duplicate information readily available in public documents.



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